UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,617	04/25/2005	Wenlong Deng	53624/DBP/C306	1639

23363 7590 07/25/2008
CHRISTIE, PARKER & HALE, LLP
PO BOX 7068
PASADENA, CA 91109-7068

EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
07/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,617	DENG, WENLONG	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16* is/are pending in the application.

4a) Of the above claim(s) *13,14 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-12 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Please note that the Examiner assigned to this case has changed. The Examiner's contact information can be found at the closing of this Office action.

Claims 11-16 are pending in the application.

Election/Restrictions

Claims 13-14 and 16 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/20/08.

Claims 11-12 and 15 were examined on their merits.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The citizenship of the Inventor states 'Chinese.' (see the substitute Oath filed on 4/25/05) This should properly state 'China' if the Inventor is a citizen of China. Correction is necessary.

Specification

The amendment filed 1/9/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The embodiments of New Matter added to this Specification is quite numerous. While it is evident that Applicants are attempting to amend the specification to be more clear, the meanings of many words and/or phrases which have been added change the scope of what would reasonably be considered to be the breadth of the disclosure as originally filed. There are so many instances of New Matter, it would be exhaustive for the Examiner to point out each and every instance of new matter, however, some examples appear below:

OS=Original Specification AS= Amended Specification

Page 3, line 6:

OS- lower side effect to the artificial anti-rheumatic medicine.

AS- lower side effects than synthetic artificial anti-rheumatic medicine.

Here, the term 'synthetic' is new matter because the OS did not specify 'synthetic' which is a 'species' of an artificial medicine.

'Another useful resin is D10...manufactured by Nankai University Resin Factory Tianjin' is New Matter. Applicant cannot newly disclose information which was not present in the original disclosure as filed; hence, this entier statement is New matter.

Applicant is required to cancel all of the new matter in the reply to this Office action. It would be helpful if Applicant would accept the entire removal of the specification entered on 1/9/2007 and amend the specification accordingly using the first specification as a template without the addition of new matter into the specification.

The Specification is further objected to for the recitation of 'macroscopic void adsorbent.' While it is known in the art that certain resins will produce spaces referred to as a 'macroscopic void', 'macroscopic void' is not a type of resin such as anion or cationic exchange resin. Clarification is necessary.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-12 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for treating rheumatism consisting of an alcoholic extract of T. hypoglaucum, E.brevicornum, L.barbarum L., C.chinensis L., does not reasonably provide enablement for treatment of rheumatism with a crude mixture of these plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of

experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

(1) Breadth of the claims

Applicants claim a pharmaceutical mixture for treating rheumatism consisting of the above-cited plants. While claim 11 for example, recites plant matter, the claims are given their broadest reasonable interpretation in light of the disclosure. The plants as claimed are deemed to also read on extracts of the plants because the specification refers to the plants as extracts. This is especially true in light of the original disclosure in which claims 4 and 5 indicate that the plants may be individual compounds extracted from the plants, or alternatively, can be more crude extracts. Because limitations from the specification are not read into the claims, and because Applicants have not specifically defined what the plant names mean, it is deemed that the plants, as recited in claims 11, 12 and 15 are directed toward the plants themselves or any crude or purified extract thereof or any active ingredient thereof including crude or purified extracts or active ingredients which are not explicitly taught by the Specification.

(2) Amount of guidance present in the disclosure

The disclosure provides two methods for making the 'invented medicine.' The first method is found on pages 7-8 of the Specification, as amended on 1/9/1007, whereby a semi-purified extraction of the plants has taken place. The second method for making the 'invented medicine' is found on page 9 which discloses a crude alcoholic extract of the plants.

Additionally, while the method for making the individual compounds which can be used as the 'inventive medicine' is not disclosed, Applicants have indicated that certain compounds can be substituted for the plant matter of the claims (see, for example, original claim 4). However, Applicants disclose that Epimedium brevicornum may be replaced by icarine for example, that Tripterygium hypoglaucum can be replaced by diteerpenoids, triterpenoids and alkaloids and Lycium barbarum and Cuscuta chinensis can be replaced by flavone (it is not clear if this means one individual flavone or a plurality of flavones -see original claim 4 for example). Besides the compound of icarine obtained from E.brevicornum; diterpenoids, triterpenoids, alkaloids and flavone(s) are broad genus of phytochemicals. The skilled artisan would not have a reasonable expectation of success in the use of any specific diterpenoids, triterpenoids, alkaloids and flavone(s) from the identified plant because these compounds are structurally highly diverse within their own respective genera. Applicants are directed toward Hanson, J. (1999) who reported various species of diterpenoids (see entire reference). It is plainly evident that the broad genus of diterpenoids for example,

expands from a small basic core structure, however, each compound is gravely different possessing unique functional groups. Further, it does not appear that Applicants have elucidated any particular structures of diterpenoids, triterpenoids, alkaloids or flavones and it is not known if the prior art has elucidated every diterpene, triterpenoid and alkaloid from T. hypoglaucum or flavones from L.barbarum or C.chinensis. It would be therefore be *a priori* unpredictable to ascertain which specific compounds would be effective in the Instantly claimed composition. The skilled artisan would need to perform tedious trial and error protocols in order to ascertain what combination of particular elements will work in the broadly claimed invention.

It is accepted that each of the methods for preparing the herbal extracts as described on pages 7-8 (the 'first' method), the method described on page 9 (the 'second method') will provide for the claimed effects. However, Applicants are broadly claiming a composition for treating rheumatism with the crude herb or any extract or any ingredients (active or inactive) of the herbs for treatment of rhumatism. Hence, it is decided that the claimed invention is not enabled for its *broad scope*.

While it is accepted that the product (extract) obtained from the first method for extraction of the plant will provide for the claimed effects, it is decided that this method is not enabled. One of skill in the art would not be able to practice this extraction protocol absent undue experimentation. This is because the Specification teaches that the protocol employs a resin named 'WLD' which is manufactured by CTM Institute of

Sichual Province. (see page 8 of the amended specification of 1/09/2007). The Examiner cannot find any information regarding 'WLD' resin; i.e., the Examiner cannot find what this resin consists of. Additionally, while Applicants have also added into the Specification 'Another useful resin is D101 ...' (this embodiment being new matter as discussed previously). the characteristics of this resin are also unknown. The skilled artisan, lacking any information with regard to this resin, would not be able to reproduce the extract of this method; it would be impossible because the specification does not elucidate this product obtained from the protocol and hence, the skilled artisan would never know if they were in possession of such an extract. For example, considering that the characteristics of WLD resin and D 101 resin are unknown, the skilled artisan could not even guess what type of resins these are, and thus the skilled artisan would not be enabled to carry out this protocol.

(3) State of the Art, Unpredictability in the Art

The state of the art is unpredictable with regard to plant extracts. The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results

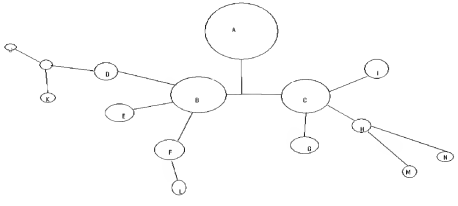
are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work (see MPEP § 2164.04)

It is well known in the art that polarity of solvents plays a key role in determining the final product obtained by an extraction. However, because many phytochemicals remain undiscovered, the skilled artisan has to make his best educated guess as to what types of phytochemicals will be successfully extracted with a solvent of a particular polarity. Often times, unless the constituents in a particular plant extract have been well evaluated and documented in the literature, the skilled artisan must adhere to trial and error protocols in order to quantitatively determine phytochemical constituents present in samples obtained from respective extraction procedures. These procedures are common when, for example, a plant or part thereof has been documented in the literature as possessing some medicinal quality. The skilled artisan will attempt numerous extraction protocols in attempt to isolate the particular ingredient which has this medicinal quality. Typically, beginning with the first crude extraction, it is a guess

as to weather or not the extract will possess certain phytochemical constituents. It is noted that the Instant specification does not disclose what the active ingredient of the extract is; on the contrary, the specification only teaches certain extracts which provide for the effective ingredient.

Each successive extraction of plant matter yields different products due to the exclusion of ingredients based on the polarity of the solvents solvating constituents with similar polarities. Subsequently, the properties of each respective product are unpredictable and would need to be evaluated for chemical constituents. The following is an illustrative example of the many products which may be produced by different successive extraction

protocols:



In this example, assume that A= the initial water extract from a homogenized sample of grape. The water extract from the grape is then subjected to a methanol/water extraction to form products B (soluble with methanol) and C (more soluble with water). Product C is then extracted in a seperatory funnel with three organic solvents: chloroform, benzene and ethyl ether to form products G, H and I which solvate with the respective solvents based on the polarity of the inherent constituents. Product H, which we will assume is the product obtained in the benzene fraction, is extracted again in a seperatory funnel with benzene and methanol to remove any residual methanol-soluble constituents. The additional circles represent extractions which may be done to obtain different products, using similar solvents as discussed previously, or entirely different solvents. Consequently, the characteristics of each respective product would need to be evaluated for chemical constituents. This representation is indicative of the vast array of distinct products which may be obtained due to the ***enormity of possible extraction permutations***.

Unpredictability with regard to plant extracts due to their highly complex nature has been well documented in the art. Revilla et al. for example (1998) showed that the ***slightest variations in polarity of solvent and reaction time*** upon grape extraction ***provided respective products with unique characteristic properties*** (See Tables 1, 2, 4, 5, 6 and 7). In turn, each product would possess varying pharmacological properties based upon their respective methods of extraction. Further contributing to

the unpredictability of plant extracts, it has been determined that in some cases, the active agent is not a single ingredient, but a combination of ingredients working synergistically to provide a therapeutic effect:

> "The blood red sap from the bark of several species of Croton (Euphorbiaceae) are used in traditional medicine in S. America to treat wounds and a series of diseases including cancer. More than 90% dry weight of the sap consists of mixtures of proanthocyanidins ranging from monomers to heptamers and even to polymers of twenty units. We have established the chemical structures of these oligomers and the monomeric units are either catechin or gallocatechin…In addition, we isolated some novel diterpenoids and a series of simple phenols as minor constituents. As a result of biological tests we have concluded that here is no single ingredient for would healing but that the whole sap contributes to the healing process" (Phillipson, J. 1999).

Accordingly, in light of the grave unpredictability in the art with regard to plant extracts, the claims are not enabled for any extract as Instantly claimed. Each product obtained from an extraction is quite unpredictable in nature. Even the most skilled of artisans would need to quantify each product for constituents as well as medicinal efficacy. Considering this evidence, the skilled artisan, lacking information with regard to any other solvents or active ingredients obtained from the claimed plants which will produce the Instantly claimed phytochemicals, would necessarily need to perform tedious trial and error protocols without expectation of success in order to ascertain

what other extracts would provide for the specific therapeutic uses as described in the claims.

Claims 11-12 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The totality of the enablement rejection as set forth *supra* may be applied here. While the Written description requirement is different, and separate from the Enablement requirement, the Enablement requirement set forth *supra* clearly conveys the unpredictable nature of plant extracts for use in medicine.

It is deemed that Applicant was not in possession of the broad scope of pharmaceutical mixtures as Instantly claimed for treating rheumatism, nor has applicant provided a representative number of examples from this broad genus for treating rheumatism. Applicants have shown one enabled embodiment within the Instant specification; that being an alcohol extract of the claimed herbs for treating rheumatism.

Applicants, while broadly disclosing that some genera of compounds from T. hypoglaucum, L. barbarum and C. chinensis may be used in place of the extracts

therefrom, have not elucidated any specific compounds from these plants, nor have Applicants described compounds from this plant in such a manner in order to provide a clear nexus between the type of compound which will be useful in treating rheumatism. As plainly evident by Hanson, J. (1999), diterpenoids for example, fall under a large, diverse class of pharmaceutical compounds possessing different functions and effects (again, see entire reference). Hence, it is not deemed that Applicants have provided a nexus between specific elucidated phytochemicals from these plants (as a whole) and a treatment for rheumatism; that is, that one of ordinary skill in the art would not know what specific diterpenoid, triterpenoid or flavone for example, will provide for the claimed effects in that Applicants have not disclosed any particular compounds which would be useful.

Limiting the claims to an alcoholic extract of the claimed plant materials will overcome these rejections made under 35 USC 112 First paragraph.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

/Patricia Leith/
Primary Examiner, Art Unit 1655